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| PRE-APPEAL BRIEF REQUEST FOR REVIEW | | Docket Number (Optional) 1291.1142101 | |
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| | | First Named Inventor GENE P. DIPOTO | |
| | | Art Unit 3733 | Examiner JAMES L. SWIGER, III |

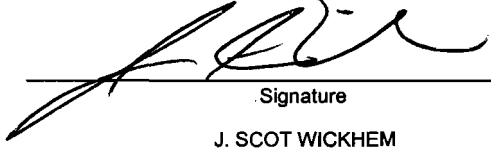
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. ☒

This request is being filed with a notice of appeal. ☒

The review is requested for the reason(s) stated on the attached sheet(s). ☒
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)
- ☒ attorney or agent of record.
Registration number 41,376
- ☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____


Signature
J. SCOT WICKHEM
Typed or printed name

612.677.9050
Telephone number

SEPTEMBER 28, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: GENE P. DIPOTO Confirmation No.: 9623
Serial No.: 10/693,663 Examiner: JAMES L. SWIGER, III
Filed: OCTOBER 24, 2003 Group Art Unit: 3733
Docket No.: 1291.1142101 Customer No.: 28075
Title: METHODS AND APPARATUSES FOR FIXATION OF THE SPINE
THROUGH AN ACCESS DEVICE

PRE-APPEAL CONFERENCE BRIEF

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Thu H. Le-To

SEPTEMBER 28, 2007

Date

Dear Sirs:

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 1-4, 6-12, 14-18, and 23-32 are rejected as being unpatentable over Davison (US 6,530,926) in view of Cornwall et al. (US 6,485,518). Claims 19-22 are separately rejected as being unpatentable over Davison in view of Cornwall et al. Applicant respectfully submits the rejections are made in error.

Regarding independent claims 1 and 14, the Examiner has not addressed the claimed method step of "said access device is inclined from a plane that is generally perpendicular to the spine of the patient". Similarly, the element of independent claim 27, "wherein after insertion a plane extending posteriorly and including a longitudinal axis of the spine intersects said access device and where during said actuating said medial side of the access device

moves toward the spinous process" has not been addressed by the Examiner. MPEP 2143.03 states, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)." The Examiner has not indicated where such a teaching, suggestion, or motivation for performing such method steps can be found, thus the rejection is in error.

In the Response to Arguments section of the final Office Action, at page 5, the Examiner asserts that Cornwall teaches a screw or fixation device going through a first vertebrae and into a second one, and that to perform this procedure, access to the spinal area would have been required, regardless of triangulation, and that Cornwall would ultimately fix two vertebrae relative to one another. While Applicants agree that ultimately, Cornwall does fix two vertebrae relative to one another, Cornwall specifically teaches the most preferred method involving, "the placement of facet screws 30A and 30B is carried out using the same guideframe as was used to position the bone allografts." See column 7, lines 13-15. Cornwall also teaches using other guideframes and systems, all of which appear to involve a frame to which a narrow cannula is fixed for precise angled insertion. See column 7, lines 15-37 and FIG. 4.

The Examiner appears to be asserting that one of ordinary skill in the art would disregard the specific teachings of Cornwall for inserting screws at angled orientations using the narrow cannula to achieve the advantages provided by triangular support. Cornwall appears to teach specific advantages achieved by the triangular positioning of the screws and bone implants, using the recited narrow cannula. See column 1, line 66 through column 2, line 67. Further, Cornwall teaches their method of using facet screws and bone allografts to provide advantages over prior methods involving pedicle screws. See column 3, lines 32-40.

The example methods and systems disclosed in Davison directed at using an expandable elongate body for inserting separate fasteners into separate vertebrae and then using a fixation element to connect the fasteners appear to be quite different and involve different method steps and equipment than the method of Cornwall. In particular, Cornwall teaches, "the present narrow bone allografts are more easily inserted into the patient through a (narrower) cannulated passageway." See column 2, lines 47-49. Cornwall then teaches, "[m]ost preferably, the placement of facet screws 30A and 30B is carried out using the same

guideframe as was used to position the bone allografts," and "cannula 72 is angled to facilitate the positioning of one of facet screws 30 therethrough in a transfacet approach." See column 7, lines 13-15 and 26-28 and FIGS. 3-4. Cornwall thus appears to teach a preferred method and system involving inserting 2 facet screws, where each screw is inserted through a separate narrow cannula at a specific angle through two vertebra.

As discussed in the response filed February 20, 2007, at page 10, third paragraph, it would appear that if an enlarged/expandable elongate body, as discussed in Davidson, were used in the method disclosed in Cornwall, it would defeat the purpose of Cornwall's specifically oriented guideframes that orient narrow cannulae to deliver narrow implants to specific locations at specific orientations. In other words, Cornwall thus appears to teach away from replacing their narrow cannula in the facet screw placement procedure with the enlarged/expandable elongate body, as discussed in Davidson. In the Advisory Action the Examiner argues that Cornwall also teaches that separate components may be installed sequentially through a cannula. However, this insertion taught by Cornwall is through the specific narrow cannula described as providing the advantages discussed above.

Further, there does not appear to be any motivation or suggestion for one of ordinary skill in the art to attempt to perform the method of Davison by substituting the step of Cornwall of inserting a single screw through two vertebrae in order to provide transfacet fixation for keeping the vertebrae from moving relative to one another, as asserted by the Examiner. Davison already teaches a method of fixing adjacent vertebrae such that they do not move relative one another, using separate screws for each vertebrae and a fixation member to join the screws. Each of Davison and Cornwall appear to teach different methods and apparatus for fixing two vertebrae. The Examiner has not provided any reasoned statements or specific motivation from a reference as to why one of ordinary skill in the art would have been motivated to modify the method of Davison by using the single screw of Cornwall. Additionally, as discussed above, such a modification would appear to frustrate the purpose of Cornwall. The Examiner has thus not met the burden of establishing a *prima facie* case of obviousness.

MPEP 2143.01 III states, "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the

desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)... Although a prior art device 'may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so.' 916 F.2d at 682, 16 USPQ2d at 1432.)." The Examiner appears to be asserting that one of ordinary skill in the art could modify the methods of Davison and/or Cornwall to achieve the methods as claimed, however, such assertion cannot support an obviousness rejection.

Applicants also respectfully point out that dependent claim 10 recites the added step of delivering a second fastener through the same access device used to deliver the first fastener, where the second fastener is advanced through the first vertebra and into the second vertebra. Independent claim 23 recites delivering first and second fastener through a single access device to first and second surgical locations, respectively. The Examiner has not addressed these claims. Cornwall appears to teach advancing first and second screws into first and second vertebrae through separate cannulas at specific different angles. See column 7, lines 9-28. Davison appears to teach inserting a single screw in each of two or more vertebra and then connecting the screws using a fixation member. Neither Davison nor Cornwall appear to teach or suggest each and every element of claims 10 and 23. Thus, even if one were to combine Davison and Cornwall, one would not arrive at the methods as claimed. As discussed above, MPEP 2143.03 states that in order to establish prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. For at least the reasons set forth above, all of the claim limitations are not taught or suggested by Davison and Cornwall et al. The rejection is thus in error.

Claims 5 and 13 are rejected as being unpatentable over Davison (US 6,530,926) in view of Cornwall et al. (US 6,485,518) as applied to claims 1 and 8 and further in view of Naubardt (US 5,196,015). As discussed above, there is no motivation for one of ordinary skill in the art to combine Davison and Cornwall, and even if such a combination were made, the elements of independent claim 1, from which claims 5 and 13 depend, are not taught or suggested. Naubardt does not appear to provide what Davison and Cornwall lack. Naubardt does not appear to provide any motivation or suggestion for modifying Davison and/or Cornwall to achieve the method steps recited in independent claim 1, or dependent claims 5 and 13. This rejection is thus in error.

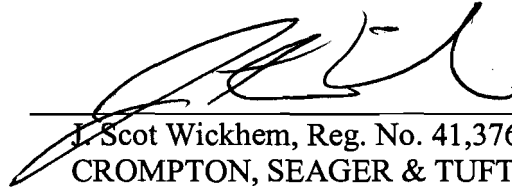
Reconsideration and reexamination are respectfully requested. It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney.

Respectfully submitted,

GENE DIPOTO

By his attorney,

Date: September 29, 2007



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